# EXHIBIT 2

**UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF OHIO EASTERN DIVISION**

| | | |
|---|---|---|
| **IN RE: NATIONAL PRESCRIPTION OPIATE LITIGATION** | ) | **MDL No. 2804** |
| | ) | |
| | ) | **Case No. 1:17-md-2804** |
| **THIS DOCUMENT RELATES TO:** | ) | |
| *Track One Cases* | ) | **Judge Dan A. Polster** |
| | ) | |

# EXPERT REPORT OF MATHEW C. GREIMEL

Confidential – Subject to Protective Order

TABLE OF CONTENTS

Introduction

My name is Matthew Greimel and I prepared this report in my capacity as an independent expert. I was retained by counsel for Defendant HBC Service Company ("HBC" or "HBC/Giant Eagle") to serve as an expert in the multi-district litigation captioned *In re National Prescription Opiate Litigation*, Case No. 17-md-2804 (the "Litigation"). This report is intended to comply with Rule 26(a)(2) of the Federal Rules of Civil Procedure.

I have a bachelor's degree in psychology from Rutgers University, Newark and have received additional training and certifications from the Newark Police Academy and the Drug Enforcement Administration ("DEA") Academy. From 2001 to 2005, I served as an officer in the Newark Police Department. From 2004 to 2005, the Police Department loaned me to the DEA as a Task Force Officer with the High Intensity Drug Trafficking Area Task Force. I joined the DEA as a Special Agent in 2005. I retired from the DEA in 2018. I am currently an independent consultant.[1]

With the DEA I was recognized 12 times for outstanding performance and for leading significant investigations. I also received the U.S. Attorney for the District of New Jersey Award for outstanding investigation (and was the first DEA Agent to receive this award). The New Jersey Narcotics Enforcement Officers Association awarded me two commendations for leading extremely impactful investigations against violent organizations. The Newark Police Department awarded me approximately 50 Command Citations for excellent police work, a Commendation from the Chief of Police for Professionalism, the FOP Honor Award for outstanding police work, and several Departmental Awards for excellent police duty. In 2003, I was awarded the Newark Municipal Resolution/Commendation for Heroism.

I am being compensated at a rate of $200 per hour for my consulting services and preparation of this report, plus expenses. I will charge $250 and hour for time spent testifying in a deposition or at trial. I have no authored publications to disclose and have not testified as an expert during the previous four years.

I. Summary of Opinions

Counsel for HBC have asked me to provide my opinion regarding:

A. The suspicious ordering monitoring provisions of the 1970 Controlled Substances Act and its regulations;

B. HBC and/or Giant Eagle's statutory and regulatory obligations under the 1970 Controlled Substances Act and its regulations;

C. The controls instituted by Giant Eagle at HBC and other distribution facilities[2] to comply with the suspicious order reporting and anti-diversion provisions contained

[1] I have attached my resume at Appendix A to this Report. In drafting this report, I considered the documents cited herein and those listed in Appendix B.

[2] This report focuses on Giant Eagle's HBC facility because that facility is the only Giant Eagle defendant in this litigation. The report, however, occasionally references Giant Eagle's successor facility, Giant Eagle Rx Distribution Center ("GERX"). It is my understanding that HBC has provided discovery related to GERX but that GERX is not

in 21 C.F.R. §§ 1301.71, 1301.74 and Giant Eagle's and/or HBC's compliance with such provisions;

D. The causes of diversion of controlled substances, including the methods employed by those who seek to fill prescriptions in order to divert controlled substances (i.e. pharmacy customers who are not seeking controlled substances to treat a legitimate medical need).

Based on my review of the evidence in the Litigation, I have concluded with a reasonably degree of certainty that:

A. Based upon my experience as a Newark Police Officer and DEA Agent, the main causes of the diversion of controlled substances from the pharmaceutical industry's closed system are: (1) independent pharmacies and internet pharmacies that have little or no controls against diversion and lack adequate management supervision, (2) medical professionals improperly writing illegitimate prescriptions for compensation, and (3) drug abusers obtaining prescriptions via false pretenses and/or creating fraudulent prescriptions.

B. Any assessment of Giant Eagle's HBC distribution operations must consider facts specific to HBC's operations. For this reason, any assessment of HBC must consider, among other things, that the facility: (1) was a captive self-distributor that only distributed to associated Giant Eagle pharmacies, which were part of and contained within regional Giant Eagle grocery stores, (2) only distributed hydrocodone combination products during the period that the DEA listed those products as Schedule III controlled substances, (3) never distributed Schedule II controlled substances.

C. HBC/Giant Eagle instituted a monitoring system for its controlled substances that placed controls at numerous points throughout Giant Eagle's self-contained distribution pipeline. These systems were sometimes redundant but served as additional checks to ensure compliance with the Controlled Substances Act.

D. The DEA's inspections and audits of HBC/Giant Eagle's distribution operations never resulted in recommendations for changes, citations for violations, or any other adverse actions. HBC/Giant Eagle therefore reasonably believed that the system it designed for its particular circumstances was appropriate and compliant with the Controlled Substances Act.

E. Giant Eagle's distribution operations—including its distribution facilities at HBC and GERX—were at all relevant times in compliance with the "security requirement" contained in 21 C.F.R. §§ 1301.71, et seq.

otherwise part of this litigation. Nevertheless, with limited exceptions, my opinions and conclusions in this report apply with equal force to Giant Eagle's GERX warehouse and distributions operations.

## II. Background

Numerous expert reports in this litigation have referenced and explained (1) the history, organization, and enforcement priorities of the DEA; (2) federal statutes and regulations relating to controlled substances; and (3) other governmental and industry guidance related thereto. For this reason, I offer only a short overview of these issues here and am advised that additional analyses will be included in the forthcoming expert reports of Sandra K.B. Kinsey, Larry Holifield, and Gregory K. Bell, among others.

### A. Diversion

Diversion is the technical term for when prescription medications are misappropriated away from their intended and legal use. For example, if a doctor writes a prescription for a narcotic to be used by a patient to treat a legitimate medical need, but the patient sells the medication—or someone steals the medication—the narcotic has been diverted. Likewise, if a doctor writes a narcotic prescription in the absence of a legitimate medical need, and the patient fills the prescription, the narcotic has been diverted.

The latter case is a concern for pharmacies, which try to ensure that they are not filling prescriptions that doctors have written for anything other than a legitimate medical need. Fortunately, approximately 99.5 percent of physicians are not writing prescriptions that divert narcotics.[3] Nevertheless, in my opinion, the primary causes of diversion are over-prescribing, drug seeking patients, and internet pharmacies that make little to no effort to differentiate between prescriptions that appear to be diversionary and those that are serving a legitimate medical purpose.[4]

As a police officer and DEA Agent, I saw how these circumstances can lead to diversion. I also observed that people seeking to obtain prescription drugs for something other than a legitimate medical need rely upon independent pharmacies and internet pharmacies rather than large chain drug stores. In my opinion, this is because independent pharmacies and internet pharmacies tend to have weaker diversion controls and, as a result, are more amenable to filling questionable prescriptions.

### B. Controlled Substances Act and the DEA

The United States Government passed the Controlled Substances Act in 1970 (the "CSA" of the "Act"), setting the stage for increasing regulation over the manufacture, distribution, sale, and use

[3] *See* Prevoznik Dep., Ex. 14, Apr. 17, 2019 (DEA Deputy Administrator Rannazzisi's testimony before the House of Representatives Committee on Energy and Commerce, April 29, 2014 ("I think that if you are talking about 99.5 percent of the prescribers, no, they are not overprescribing, but our focus is in rogue pain clinics and rogue doctors who are overprescribing.")). During his deposition, DEA Unit Chief Thomas Prevoznik testified that one to two percent of prescribers are overprescribing. Prevoznik Dep. 401:10-17. In my opinion, this distinction is negligible.

[4] The Cuyahoga County Opiate Task force identified three examples of "[w]idespread diversion": (1) doctor shopping, (2) illegal online pharmacies, and (3) the establishment and recent closure of pill mills. "Widespread diversion," in turn, is listed among six causes of the "prescription drug abuse" epidemic, which include "[i]mproper storage and disposal of unused medication," "[o]ver-prescribing," and "substance abuse and underlying mental health issues." CUYAH_000018534 – CUYAH_000018535.

of narcotics.[5] The purpose of the Act was to amend the Public Health Service Act and other laws to "provide increased research into, and prevention of, drug abuse and drug dependence; to provide for treatment and rehabilitation of drug abusers and drug dependent persons; and to strengthen existing law enforcement authority in the field of drug abuse."[6] The Act placed all controlled substances that the federal government regulated under existing law into one of five schedules based upon the substance's "medical use, potential for abuse, and safety or dependence liability."[7] When determining the schedule of a drug, or whether a drug may be decontrolled, the Act requires that the Attorney General consider the following factors:

> (1) Its actual or relative potential for abuse.
> (2) Scientific evidence of its pharmacological effect, if known.
> (3) The state of current scientific knowledge regarding the drug or other substance.
> (4) Its history and current pattern of abuse.
> (5) The scope, duration, and significance of abuse.
> (6) What, if any, risk there is to the public health.
> (7) Its psychic or physiological dependence liability.
> (8) Whether the substance is an immediate precursor of a substance already controlled under this subchapter.[8]

The law also called for the creation of regulations, providing that "[t]he Attorney General is authorized to promulgate rules and regulations and to charge reasonable fees relating to the registration and control of the manufacture, distribution, and dispensing of controlled substances and to listed chemicals."[9]

C. DEA Regulations

The relevant DEA regulation are at 21 C.F.R. § 1301. The controlling Section, titled "Security requirements generally" (the "Security Requirement"), provides that:

> (a)All applicants and registrants shall provide effective controls and procedures to guard against theft and diversion of controlled substances. In order to determine whether a registrant has provided effective controls against diversion, the Administrator shall use the security requirements set forth in Secs. 1301.72-1301.76 as standards for the physical security controls and operating procedures necessary to prevent diversion.[10]

Notably, the regulations allow for "substantial compliance," and leave significant discretion with the registrant.

> (b) Substantial compliance with the standards set forth in Secs. 1301.72-1301.76 may be deemed sufficient by the Administrator after evaluation of the overall security system and needs of the applicant or registrant. In evaluating the overall security system of a registrant or applicant, the Administrator may consider any of the following factors as he may deem relevant to the need for strict compliance with security requirements:

---

[5] Comprehensive Drug Abuse Prevention and Control Act of 1970, 91 P.L. 513, 84 Stat. 1236; 21 U.S.C. §§ 801 et seq.
[6] 84 Stat. 1236, at Synopsis.
[7] https://www.dea.gov/controlled-substances-act.
[8] 21 U.S.C. § 811.
[9] 21 U.S.C. § 821. The Attorney General delegated this authority to the DEA.
[10] 21 C.F.R. § 1301.71.

> (1) The type of activity conducted (e.g., processing of bulk chemicals, preparing dosage forms, packaging, labeling, cooperative buying, etc.);
> (2) The type and form of controlled substances handled (e.g., bulk liquids or dosage units, usable powders or nonusable powders);
> (3) The quantity of controlled substances handled;
> (4) The location of the premises and the relationship such location bears on security needs;
> (5) The type of building construction comprising the facility and the general characteristics of the building or buildings;
> (6) The type of vault, safe, and secure enclosures or other storage system (e.g., automatic storage and retrieval system) used;
> (7) The type of closures on vaults, safes, and secure enclosures;
> (8) The adequacy of key control systems and/or combination lock control systems;
> (9) The adequacy of electric detection and alarm systems, if any including use of supervised transmittal lines and standby power sources;
> (10) The extent of unsupervised public access to the facility, including the presence and characteristics of perimeter fencing, if any;
> (11) The adequacy of supervision over employees having access to manufacturing and storage areas;
> (12) The procedures for handling business guests, visitors, maintenance personnel, and nonemployee service personnel;
> (13) The availability of local police protection or of the registrant's or applicant's security personnel;
> (14) The adequacy of the registrant's or applicant's system for monitoring the receipt, manufacture, distribution, and disposition of controlled substances in its operations; and
> (15) The applicability of the security requirements contained in all Federal, State, and local laws and regulations governing the management of waste.

The DEA has clarified the discretionary nature of this provision—as well as the fact that a registrant's "substantial" rather than "strict" compliance can constitute sufficient compliance with the regulation.[11] Based on my work at the DEA, this is also my understanding of the Controlled Substances Act and its regulations.

One of the "standards" referenced in § 1301.71 is particularly relevant to this Litigation. Section 1301.74(b) instructs registrants to "design and operate a system to disclose to the registrant suspicious orders of controlled substances" and to "inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant." The section further explains that suspicious orders "include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency."

It is important to note that a suspicious order is distinct from a diverted order. Even if a concern about size, pattern, or frequency brings an order to a registrant's attention, in most cases the registrant's investigation reveals that the cause for concern is wholly innocuous. And in the rare cases in which the cause cannot be identified or the order is deemed suspicious, that still does not mean that the order compromised the closed distribution system, would or could have been diverted, or would or could have caused any harm whatsoever. This lack of a certain connection may be the reason why, in many cases, the DEA did not follow up or investigate a large portion of registrants' reports.[12]

[11] *See* Ashley Dep. 251:17 – 252:18; 253:6 – 254:5, Mar. 15, 2019 (affirming that most aspects of a distributor's efforts to monitor for suspicious orders are in the registrant's discretion); Prevoznik Dep. 395:10 – 396:18, Apr. 17, 2019; 21 C.F.R. 1301.71(b).
[12] *See* Wright Dep. 84:9 – 21.

D. Other DEA Guidance

Over the past several years, other forms of non-regulatory CSA guidance have also emerged. These forms of guidance—be they "Dear Registrant" Letters, administrative actions, or industry guidelines—are relevant but flawed as a means of giving clear direction to registrants. First, not all registrants receive or are aware of these forms of guidance. Second, they are not binding in the same manner as regulations that have gone through the formal administrative notice and comment process.

With regard to awareness, "Dear Registrant" Letters do not reach all registrants. For example, the DEA would not have sent Deputy Administrator Rannazzisi's 2006 and 2007 "Dear Registrant" Letters to HBC because HBC was not a registrant until 2009.[13] HBC was also not part of any industry organization that created suspicious order monitoring guidelines for its members.[14]

The DEA has also consistently taken the position that notice-and-comment rulemaking has advantages that other forms of guidance lack. This is because, "it has the benefit of availing agencies of more complete information about a proposed rule's effects than the agency could ascertain on its own and therefore results in better decision making by regulators."[15] For this reason, the Attorney General has advised that "guidance may not be used as a substitute for rulemaking and may not be used to impose new requirements on entities outside the Executive Branch."[16]

III. Controls Across Giant Eagle's Operations

While the DEA's regulations state that suspicious orders "include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency," the regulations do not provide any instruction or guidance on how to apply these criteria.[17] In short, the regulations do not state what a registrant must do in order to ensure compliance with the security requirement, instead suggesting that any particular framework depends on the operations of the particular registrant.[18]

In response to this grant of discretion, Giant Eagle properly placed controls across its distribution pipeline—from the warehouse to the corporate office to the pharmacy. By using a system with multiple points of detection, Giant Eagle provided effective controls and procedures to guard against theft and diversion. For this reason, and based on my training and experience as a DEA Agent, it is my opinion that this system met the security requirements in §§ 1301 et seq. and

[13] *See* Tsipakis Dep. 22:22 – 23:1, Dec. 13, 2018; *see also* Tsipakis Dep. Ex. 13 (Omnibus exhibit containing December 27, 2006 "Dear Registrant" Letter; December 27, 2007 "Dear Registrant" Letter; February 7, 2007 "Dear Registrant" Letter; and June 12, 2012 "Dear Registrant" Letter). Though one would expect that HBC received the 2012 "Dear Registrant" letter, there is no evidence that it did. *See* Tsipakis Dep. 123:21 – 124:6. Further, while the 2012 "Dear Registrant" letter makes general reference the 2006 and 2007 Letters, it does not explicitly explain or expound on the guidance provided in those letters.

[14] *See* HBC's Serv. Co.'s Second Supp. Answer to Pls.' Interrog. No. 7, March 29, 2019.

[15] Prevoznik Dep., Ex. 10 at 1 (Mem. from the Attorney General to All Components re Prohibition on Improper Guidance Documents, Nov. 16, 2017).

[16] *Id.*

[17] *See* Wright Dep. 106:6-15, Feb. 28, 2019.

[18] *See, e.g.*, Wright Dep. 102:11 – 103:13, 128:1 – 129:22, Feb. 28, 2019.

therefore complied with the DEA's standards in all relevant respects, especially considering that HBC was both a captive self-distributor and only distributed Schedule III-V controlled substances.

A. Controls at the Warehouse

The controls at Giant Eagle's HBC warehouse were extensive and effective in preventing diversion. The design divided the warehouse into different sections, with the section that housed relevant controlled substances fenced in a cage that went from floor to ceiling.[19] HBC kept the cage locked with 24-hour monitoring.[20] Pickers conducted inventory counts of the cage's contents at least five (5) times a day, to ensure that product was not missing or misappropriated.[21] The warehouse also utilized a Vocollect System that allowed Giant Eagle to track the selection and packing of the product.[22]

The pickers at the warehouse also applied their experience and knowledge of customary and regular orders to determine if an order should be deemed "suspicious" and therefore flagged for investigation.[23] For example, HBC's warehouse controls caught orders that were flagged for investigation due to the unusual amount of the order or its deviation from a pattern.[24] Those orders would then be further investigated by a warehouse or corporate member to determine the underlying cause of the nonconformity.[25]

B. Controls at the Corporate Office

At the "corporate" level, Giant Eagle applied another level of monitoring. This separate oversight proved to be redundant but continued to ensure that HBC products were secure at all times. Based at corporate headquarters, Giant Eagle's procurement team monitored the inventory level of all medications regardless of their classification.[26] Utilizing their training and experience, members of the procurement team identified orders of interest by noting spikes and deviations in the quantity of products being ordered and shipped to the warehouse.[27]

Giant Eagle also implemented a threshold monitoring system in 2013, which received several updates in the ensuing years, including a new system following Giant Eagle's 2016 transfer of pharmacy warehouse and distribution operations to the Giant Eagle Rx Distribution Center

[19] Durr Dep. 36:4-15, Jan. 22, 2019.
[20] *Id.*
[21] Durr Dep. at 159:17 – 160:1, Jan. 22, 2019.
[22] Durr Dep. at 83:14 – 85:15, Jan. 22, 2019.
[23] Durr Dep. at 91:8 – 92:23, Jan. 22, 2019.
[24] *See, e.g.*, Bianco Dep. 66:19 – 67:5, Jan. 18, 2019; Bianco Dep., Ex. 6; HBC_MDL00090011. These orders, however, proved not to be suspicious for a number of reasons, including that some were conversion factor errors. *See e.g.*, Bianco Dep. 67:22 – 69:19, 186:3 – 187:4 (explaining that conversion factors errors caused pickers to flag and stop orders).
[25] Bianco Dep. 186:3 – 187:4, Jan. 18, 2019; *see also* Durr Dep. 92:12 – 93:16, Jan. 22, 2019.
[26] Heiser Dep. 19:16-23.
[27] Tsipakis Dep. 99:1-18, Dec. 13, 2018; Durr Dep. 86:5-23, Jan. 22, 2019; Heiser Dep. 18:14 – 20:8, 51:8-21, Feb. 19, 2019; Carlson Dep. 142:11 – 143:10, Jan. 8, 2019.

(GERX).[28] When distributing from GERX, Giant Eagle also invested in additional monitoring products that helped the company review the pharmacies' purchasing and dispensing patterns.[29]

C. Controls at the Pharmacy

As explained in greater detail below, Giant Eagle's distribution operations were part of a closed system that only provided product to Giant Eagle pharmacies. And Giant Eagle imposed numerous levels of oversight to ensure that these pharmacies maintained control over controlled substances and only dispensed such substances pursuant to legitimate prescriptions.

Once a controlled substance reached the pharmacy, Giant Eagle continued to monitor the product.[30] The product was scanned and the product information was recorded electronically.[31] The pharmacy applied special storage control protocols depending on the controlled substance's schedule.[32] Only licensed pharmacists, who Giant Eagle specifically trained to monitor pharmacy inventories, were permitted to access to the locked cabinets and safes.[33] Further, Giant Eagle's loss prevention team monitored controlled substance inventories, which were also subject to internal audits.[34] And Giant Eagle Pharmacy District Leaders ("PDLs") conducted regular physical inspections of the pharmacies and their products.[35]

At the counter, Giant Eagle policies and procedures mandated that pharmacists back count each product at the point of dispensing.[36] There were daily monitoring procedures and monthly narcotics audits to ensure there was no misappropriation or diversion at the pharmacy level.[37] Pharmacist were also encouraged to scrutinize prescriptions and given full support for any decisions regarding the same.[38] Finally, Giant Eagle had a loss prevention department that would investigate any suspicions regarding diversion and/or theft at the pharmacy.[39]

---

[28] *See supra* note 2.
[29] Millward Dep. 258:2-20.
[30] Heiser Dep. 18:14 – 19:13, Feb. 19, 2019.
[31] *Id.*
[32] Tsipakis Dep. 282:4 – 283:1, Dec. 13, 2018; Chunderlik Dep. 263:7-20, Jan. 16, 2019; Mollica Dep. 62:22 – 63:5, 66:17-67:25, Jan. 4, 2019.
[33] Tsipakis Dep. 282:4 – 283:1, Dec. 13, 2018; Chunderlik Dep. 263:17-20, Jan. 16, 2019.
[34] Tsipakis Dep. 282:20-22, Dec. 13, 2018; Chunderlik Dep. 264:3-5, Jan. 16, 2019.
[35] Carlson Dep. 232:13 – 233:19, Jan. 8, 2019. Chunderlik Dep. 268:19-23, Jan. 16, 2019.
[36] Chunderlik Dep. 267:2 – 267:20, Jan. 16, 2019 (explaining that "back counting," happens "[a]fter each time a prescription goes through the filling process," when "the pharmacist is required to go back and count the remaining inventory that's in the -- for that product and log it into the electronic database within our pharmacy data management system").
[37] Carlson Dep. 232:18 – 233:23, Jan. 8, 2019; Mollica Dep. 65:22 – 66:15, Jan. 4, 2019.
[38] *See, e.g.*, Mollica Dep. 112:19 – 113:19, Jan 4, 2019; HBC_MDL00059107 (Controlled Substance Dispensing Guideline).
[39] Carlson Dep. 234:25 – 235:13, Jan. 8, 2019.

## IV. Factors Specific to Giant Eagle and HBC's Distribution Operations

### A. Types of Drugs Distributed by HBC

Throughout the relevant time period, HBC only distributed Schedule III-V Controlled Substances.[40] Further, it is my understanding that HBC only distributed one type of controlled substance—Schedule III hydrocodone combination products containing hydrocodone in combination with another painkiller or cough medicine—that is relevant to this Litigation, which is otherwise focused on the distribution of Schedule II opioids. Hydrocodone combination products, or HCPs, are relevant because the DEA reclassified the products from Schedule III to Schedule II in October 2014. And at that time, HBC—which was only registered as a Schedule III-V facility—stopped distributing HCPs.[41]

Any assessment of HBC's monitoring and controls must consider HBC's limited product line when assessing its compliance with § 1301.71.[42] Because HBC only distributed Schedule III-V controlled substances, one could expect that its monitoring controls would be less demanding than an operation distributing Schedule II controlled substances. Yet despite this diminished obligation, HBC appears to have imposed numerous controls to prevent diversion and ensure compliance with the security requirement.

### B. Type of Customers to Whom HBC Distributed

Though it is not part of the statute or its regulations, in recent years the DEA has promoted the idea that a registrant must "Know Your Customer." This catchphrase attempts to capture the DEA's concern—which arose when internet pharmacies began operating—that registrants know about the business of the entity to whom they are selling controlled substances.[43]

In this regard, HBC's controls were truly exemplary. All of HBC's (and later GERX's) customers were Giant Eagle pharmacies that were part of the same company that oversaw HBC's distribution operations. The warehouse was thus a captive operation that exclusively served Giant Eagle pharmacies. For this reason, HBC did not just know its own customers; it was its customer. Thus, it knew who was working at each pharmacy, who was managing each pharmacy, the level of corporate supervision that was imposed at each pharmacy, the location and market dynamics of each pharmacy, and the policy and controls that each pharmacy imposed from delivery to storage to dispensation.[44] HBC also never distributed to the two most significant sources of diversion: independents pharmacies and internet pharmacies. The DEA's concern with these pharmacies is well documented in other expert reports. Nevertheless, it is worth noting that numerous DEA

[40] Tsipakis Dep. 23:10-19, 73:17 – 74:8, Dec. 13, 2018; Durr Dep. 125:2-15, Jan. 1, 2019.
[41] In 2016, Giant Eagle began distributing Schedule II controlled substances after opening a successor distribution facility known as GERX. *See supra* note 2.
[42] *See, e.g.*, 21 C.F.R. 1301.71(b)(2) (listing "type and form of controlled substance handled" among the factors to consider when assessing compliance).
[43] *See, e.g.*, US-DEA-00000386; Wright Dep. 518:6 – 520:12.
[44] Tsipakis Dep. 106:18 – 107:23, Dec. 13, 2018; *see also, e.g.*, Mollica 213:19 – 215:12.

documents and DEA testimony reference these two types of pharmacies as the primary sources of diversion.[45]

C. Written Policies, Documentation, and Thresholds

None of the laws, rules, or regulations related to suspicious order monitoring require written suspicious order monitoring policies.[46] Likewise, none of the laws, rules, or regulations related to suspicious order monitoring require the documentation or retention of any due diligence related to suspicious order monitoring.[47] Rather, the law and the DEA's regulations have intentionally allowed registrants to design their own procedures around these issues.[48]

Despite the absence of any such requirements, Giant Eagle and HBC always had monitoring procedures, including written procedures. Numerous pharmacy-level procedure documents sought to prevent diversion.[49] There were also numerous security procedures and protocols serving the same purpose at the warehouse.[50] Finally, the documentary record in this litigation shows formal inventory control and suspicious order monitoring policies in 2014.[51] However, based on additional testimonial and documentary evidence, I understand that these 2014 documents were reformatted versions of earlier documents that Giant Eagle did not formally retain.[52] Nevertheless, HBC has been able to find and produce some examples of these pre-2014 policy documents.[53]

In 2013, Giant Eagle and HBC instituted a computerized threshold system for suspicious order monitoring. As already noted, the law and regulations leave the means and method of detecting suspicious orders to the registrant's discretion.[54] As a result, a threshold system was not

[45] *See, e.g.*, Rannazzisi Dep. Ex. 9 (Hearing before the Committee on the Judiciary, United States Senate, *Rogue Online Pharmacies: The Growing Problem of Internet Drug Trafficking* ("there are many websites on the Internet that 'offer' to sell controlled substances illegally. A 'Google' keyword search such as 'hydrocodone no prescription needed' reveals thousands upon thousands of hits.")); *see also* Wright Dep. 89:17-21, Feb. 28, 2019; Wright Dep., Ex. 10; Prevoznik Dep. 158:1-15, Apr. 17, 2019; Rannazzisi Dep. 197:18 – 200:23, 216:2-10, 217:22-24, Apr. 26, 2019, Rannazzisi Dep., Ex. 10.

[46] *See* 21 U.S.C. §§ 801 et seq.; 21 C.F.R. §§ 1301.71 et seq.; *see also* Prevoznik Dep. 357:23 – 359:1, Apr. 17, 2019.

[47] *See* 21 U.S.C. §§ 801 et seq.; 21 C.F.R. §§ 1301.71 et seq.; *see also* Wright Dep. 143:1-12, Feb. 28, 2019.

[48] *See, e.g.*, Wright Dep. 344:5 – 345:8, Mar. 4, 2019. Wright Dep., Ex. 31.

[49] *See, e.g.*, HBC_MDL00126695, HBC_MDL00080675, HBC_MDL00058107, HBC_MDL00043955, HBC_MDL00133287.

[50] Durr Dep. 33:16 – 36:17, 91:8 – 92:23, 154:23 – 155:8, Jan 22, 2019; Tsipakis Dep. 94:18 – 95:10, 111:11 – 112:11, Dec. 13, 2018.

[51] *See, e.g.*, HBC_MDL00133445, HBC_MDL00078638, HBC_MDL00004386, HBC_MDL00045916.

[52] Rogos Dep. 133:2-23, 144:13-18, Feb. 22, 2019; Durr Dep. 64:19 – 65:24, 69:22 – 70:23, Jan. 22, 2019. HBC reformatted its policy and procedure documents for their submission to the National Association of Boards of Pharmacy Verified-Accredited Wholesale Distributors (VAWD) accreditation. The NABP required that applicants for VAWD accreditation submit policies in a particular format. *See* Rogos Dep. 41:3-10, 70:14 – 71:8 ("What I recall is the inventory policy that was in the library of SOPs was in a different format than VAWD -- the VAWD application asked us to put the policies in.").

[53] *See, e.g.*, HBC_MDL00189099.

[54] Ashley Dep. 201:25 – 202:22, 251:17 – 252:18, Mar. 15, 2019;

necessary.[55] Nevertheless, it had become a popular method through which larger distributors monitored orders and Giant Eagle viewed it as an additional control.[56]

For these reasons, the 2013 threshold system was an unnecessary but helpful cross-check control that could enhance an already compliant suspicious order monitoring system. The system flagged orders for investigation and, while it was somewhat over-inclusive in identifying "orders of interest," Giant Eagle appears to have conducted thorough due diligence whenever an order flagged.[57] As Giant Eagle updated and revised its threshold system and processes, it also added layers of research to its due diligence procedures, including deeper analyses of the details of orders and the relevant pharmacy's activities.[58]

Thus, it is my opinion that, during the relevant period, Giant Eagle and HBC applied policies and procedures that effectively guarded against diversion and disclosed suspicious orders.[59]

D. The "No Shipping" Requirement

Some guidance from the DEA appeared to (1) require that a distributor registrant not ship a suspicious order and (2) suggest that a distributor registrant should not ship a flagged "order of interest" until the registrant had confirmed that it *was not* a suspicious order.

None of this guidance is incorporated into the CSA or the DEA's regulations.[60] In my opinion, this is because the relevance of a decision to ship a flagged or suspicious order depends on context. At HBC, the distributor and the buyer are part of the same company: Giant Eagle.[61] And because HBC only ships to Giant Eagle pharmacies, HBC maintains control over the product regardless of its location.[62] Giant Eagle can segregate the product at the warehouse or at the pharmacy. Furthermore, because of the tight controls throughout the Giant Eagle distribution process, the product can be easily located, even after it leaves the warehouse.[63]

Based on the evidence, it appears that whether HBC was able to stop a shipment of a controlled substance before it left the warehouse depended on when the order came to HBC's attention; sometimes it could stop the shipment and sometimes it could not.[64] It is important to remember,

---

[55] *Id.* at 87:16 – 89:18.

[56] *See, e.g.*, McClune Dep. 132:16-133:1, Jan. 25, 2019 ("we constantly worked on enhancing the whole threshold and controlled substance compliance program that Giant Eagle managed, which included controls at the warehouse, controls at retail. This added system to look at thresholds isn't explicitly stated in the DEA regs, but we thought it would be a redundant added process. We continued to add to and augment.").

[57] Millward Dep., Ex. 23; HBC_MDL00141974; HBC_MDL00058106.

[58] Millward Dep. 257:22 – 259:24, 262:1-263:14, Dec. 20, 2018; *see also, e.g.*, HBC_MDL00080562, HBC_MDL00060131, HBC_MDL00008497; HBC_MDL00057890, HBC_MDL00057893.

[59] Since 2006, Giant Eagle has identified—and timely reported to the DEA—two suspicious orders for buprenorphine from pharmacies outside of the jurisdiction in this litigation. It has not identified any suspicious orders in the jurisdiction nor has it identified any suspicious orders of any opioid products covered by this litigation.

[60] *See* 21 U.S.C. §§ 801 et seq.; 21 C.F.R. §§ 1301.71 et seq.; Prevoznik Dep.167: 5-12, Apr. 17, 2019.

[61] Tsipakis Dep. 104:10-22, 106:18 – 107:23, Dec. 13, 2018.

[62] Tsipakis Dep. 104:10-22, 106:18 – 107:23, Dec. 13, 2018.

[63] Carlson Dep. 239:20 – 240:18, Jan. 8, 2019; Tsipakis Dep. 173:15 – 174:8, Dec. 13, 2018.

[64] Millward Dep. 258:20 – 259:24, Dec. 20, 2018; Tsipakis Dep., Ex. 17. Notably, however, revised versions of the threshold system that were integrated into the Controlled Substance Ordering System (CSOS) always stopped orders that the system flagged before shipment. *See, e.g.*, Chunderlik Dep. 281:20 – 282:14, Jan. 16, 2019.

however, the purpose of the regulation is the prevention of diversion. There is no possibility of diversion as long as the product remains in Giant Eagle's control; Giant Eagle could always stop or reverse the distribution of a controlled substance to its customers—Giant Eagle pharmacies—if there was any concern that diversion could or would occur.[65] For this reasons, it is my opinion that the "no ship" guidance was not relevant Giant Eagle's distribution model.

E. Communications with the DEA

While HBC did not receive the 2006 and 2007 "Dear Registrant" Letters, it did have frequent in-person communications with the DEA in the form of warehouse inspections and annual audits. These personal interactions with the DEA are invaluable to both parties: they allow the registrant to present their anti-diversion systems to the DEA and they allow the DEA to see how those anti-diversion systems actually work in practice.[66]

The DEA first visited the HBC warehouse prior to its opening, during which DEA Agents reviewed the procedures and security related to the facility.[67] The DEA did not tell HBC that its controls were insufficient or that it needed to change anything.[68]

In the years that followed, the DEA made regular on-site inspections of Giant Eagle's warehouse operations and corporate offices in order to evaluate the company's distribution and monitoring procedures.[69] During these inspections, the DEA could physically inspect the facility, review a registrant's policies and protocols, and offer guidance directly to the registrant.[70] In all of these audits and inspections, the DEA never fined Giant Eagle or raised a violation.[71] It also never instructed Giant Eagle to change any of its security practices.[72]

---

[65] Tsipakis Dep. 173:15 – 174:8, Dec. 13, 2018; Heiser Dep. 18:14 – 20:8, Feb. 19, 2019; Millward Dep. 260:4-13, Dec. 20, 2018 ("…Giant Eagle distributed to itself, we were our customer, we knew everything about the characteristics of our store and had control of … the product from where it entered into the DC till it left in a prescription for an end user patient. If something needed to be quarantined and removed from dispensing stock, we had the ability to have our stores pull that aside, if necessary, to prevent it from being dispensed"); *see also* Millward Dep. 161:4-10, Dec. 20, 2018.

[66] Prevoznik Dep. 53:21 – 54:6, 289:18 – 290:20, Apr. 17, 2019.

[67] Durr Dep. 126:20 – 127:21, Jan. 22, 2019; Carlson Dep. 200:2-24, Jan. 8, 2019. The DEA also visited the GERX facility before it opened. Durr Dep. 174:21 – 175:18.

[68] Mollica Dep. 60:3 – 61:3, Jan. 4, 2019.

[69] Chunderlik Dep. 293:14-24, Jan. 16, 2018; Tsipakis Dep. 286:9-12, Dec. 13, 2018.

[70] Prevoznik Dep. 53:21 – 54:6, 289:18 – 290:20, Apr. 17, 2019.

[71] *See* Mollica Dep. 60:3 – 61:3, Jan. 4, 2019; Chunderlik Dep. 259:11-23, Jan. 16, 2019; Durr Dep. 171:16-22, Jan. 22, 2019.

[72] Mollica Dep. 60:3 – 61:3, Jan. 4, 2019; Tsipakis Dep. 274:6-18, Dec. 13, 2018. As noted elsewhere in this report, there was also an absence of other forms of communication between the DEA and HBC. The DEA would not have sent HBC the 2006 and 2007 "Dear Registrant" Letters because HBC was not a registrant at that time. And the DEA never made any presentations to HBC or Giant Eagle as part of its Distributor Initiative because that Initiative focused on the large distributors that were providing products to customers that were independent entities. Prevoznik Dep. 470:16 – 471:22, Apr. 18, 2019. This makes sense as the large distributors provided product to independent pharmacies and internet pharmacies, which were the reasonable focus of the DEA's diversion concerns. Large distributors also had to institute more controls in order to "Know" their customers and monitor distributions to those customers.

## V. Conclusion

Based on my review of the evidence in the Litigation, I conclude, with a reasonably degree of certainty, that:

A. Based upon my experience as a Newark Police Officer and DEA Agent, the main causes of the diversion of controlled substances from the pharmaceutical industry's closed system are: (1) independent pharmacies and internet pharmacies that have little or no controls against diversion and lack adequate management supervision, (2) medical professionals improperly writing illegitimate prescriptions for compensation, and (3) drug abusers obtaining prescriptions via false pretenses and/or creating fraudulent prescriptions.

B. Any assessment of Giant Eagle's HBC distribution operations must consider facts specific to HBC's operations. For this reason, any assessment of HBC must consider, among other things, that the facility: (1) was a captive self-distributor that only distributed to associated Giant Eagle pharmacies, which were part of and contained within regional Giant Eagle grocery stores, (2) only distributed hydrocodone combination products during the period that the DEA listed those products as Schedule III controlled substances, (3) never distributed Schedule II controlled substances.

C. HBC/Giant Eagle instituted a monitoring system for its controlled substances that placed controls at numerous points throughout Giant Eagle's self-contained distribution pipeline. These systems were sometimes redundant but served as additional checks to ensure compliance with the Controlled Substances Act.

D. The DEA's inspections and audits of HBC/Giant Eagle's distribution operations never resulted in recommendations for changes, citations for violations, or any other adverse actions. HBC/Giant Eagle therefore reasonably believed that the system it designed for its particular circumstances was appropriate and compliant with the Controlled Substances Act.

E. Giant Eagle's distribution operations—including its distribution facilities at HBC and GERX—were at all relevant times in compliance with the "security requirement" contained in 21 C.F.R. §§ 1301.71 et seq.

Matthew C. Greimel

Matthew C. Greimel

May 10, 2019